Available under BC PharmaCare when patients meet Special Authority criteria[1]

Prolia® (denosumab injection) is indicated:[2]

- for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- as a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- as a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- as a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- as a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- as a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling Amgen at 1-866-502-6436.

CRITERIA:[1]

For women with postmenopausal osteoporosis or men with osteoporosis with clinical or radiographically documented fracture due to osteoporosis, and who are contraindicated to oral bisphosphonates for one of the following reasons:

- Immune-mediated hypersensitivity reaction to oral bisphosphonates; **OR**
- Abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia.

For primary prevention of osteoporotic fractures in women with breast cancer who are receiving aromatase inhibitor therapy.

SPECIAL NOTES:

- Special Authority Request must include details regarding a patient's contraindication to oral bisphosphonates
- Clinical fracture is defined as a symptomatic (painful) fracture
- Radiographically documented fracture is defined as a fracture identified by X-ray (e.g. vertebral compression fracture). This may be asymptomatic

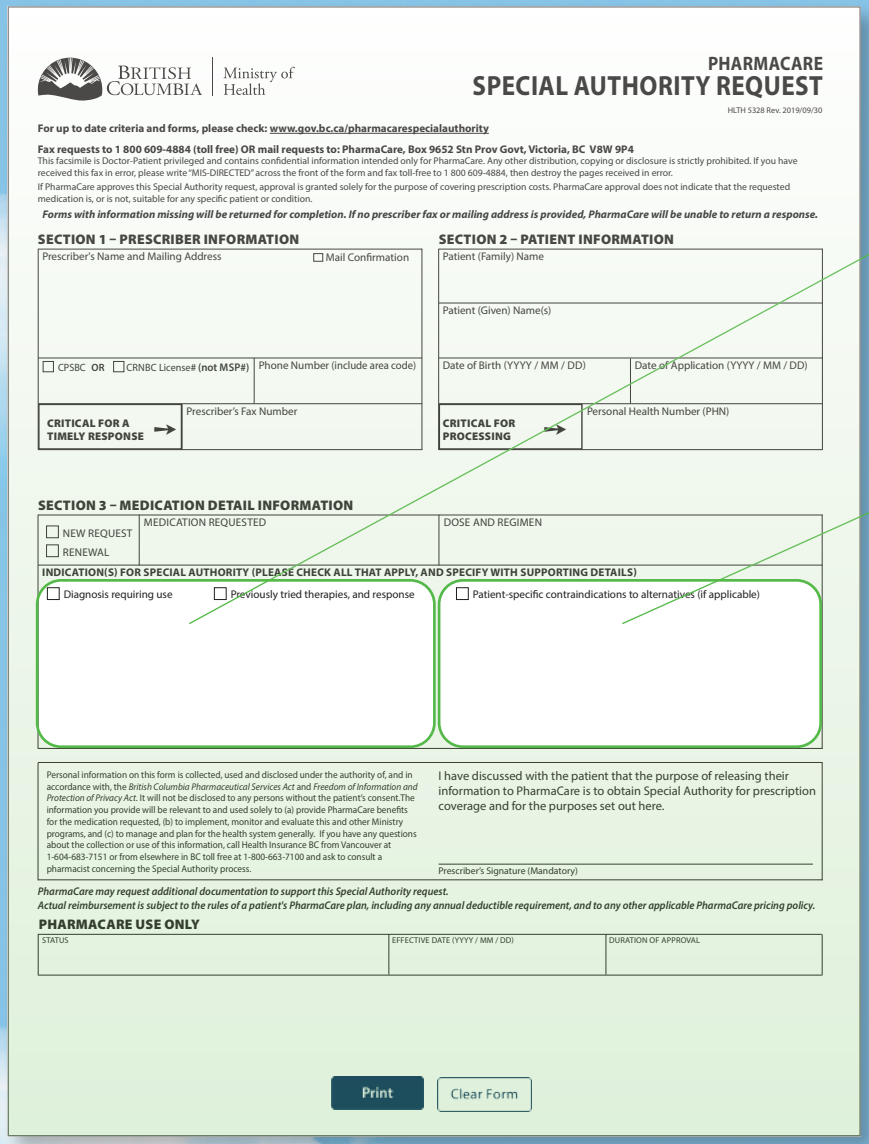
CAN-162-1022-80065-23E

Pr prolia® denosumab injection

REVIEWED BY PAAB

References: 1. British Columbia Formulary. Limited coverage drugs – denosumab. Available at: https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/prescribers/limited-coverage-drug-program/limited-coverage-drugs-denosumab. Accessed September 28, 2023.
2. Prolia (denosumab injection) Product Monograph. Amgen Canada Inc., December 21, 2022.

British Columbia Form – "How To"



BRITISH COLUMBIA | Ministry of Health

PHARMACARE
SPECIAL AUTHORITY REQUEST

HLTH 5328 Rev. 2019/09/30

For up to date criteria and forms, please check: www.gov.bc.ca/pharmacarespecialauthority

Fax requests to 1 800 609-4884 (toll free) OR mail requests to: PharmaCare, Box 9652 Stn Prov Govt, Victoria, BC V8W 9P4

This facsimile is Doctor-Patient privileged and contains confidential information intended only for PharmaCare. Any other distribution, copying or disclosure is strictly prohibited. If you have received this fax in error, please write "MIS-DIRECTED" across the front of the form and fax toll-free to 1 800 609-4884, then destroy the pages received in error.

If PharmaCare approves this Special Authority request, approval is granted solely for the purpose of covering prescription costs. PharmaCare approval does not indicate that the requested medication is, or is not, suitable for any specific patient or condition.

Forms with information missing will be returned for completion. If no prescriber fax or mailing address is provided, PharmaCare will be unable to return a response.

SECTION 1 – PRESCRIBER INFORMATION

Prescriber's Name and Mailing Address ☐ Mail Confirmation

☐ CPSBC OR ☐ CRNBC License# **(not MSP#)** | Phone Number (include area code)

CRITICAL FOR A TIMELY RESPONSE → Prescriber's Fax Number

SECTION 2 – PATIENT INFORMATION

Patient (Family) Name

Patient (Given) Name(s)

Date of Birth (YYYY / MM / DD) | Date of Application (YYYY / MM / DD)

CRITICAL FOR PROCESSING → Personal Health Number (PHN)

SECTION 3 – MEDICATION DETAIL INFORMATION

☐ NEW REQUEST
☐ RENEWAL

MEDICATION REQUESTED | DOSE AND REGIMEN

INDICATION(S) FOR SPECIAL AUTHORITY (PLEASE CHECK ALL THAT APPLY, AND SPECIFY WITH SUPPORTING DETAILS)

☐ Diagnosis requiring use ☐ Previously tried therapies, and response

☐ Patient-specific contraindications to alternatives (if applicable)

Personal information on this form is collected, used and disclosed under the authority of, and in accordance with, the *British Columbia Pharmaceutical Services Act* and *Freedom of Information and Protection of Privacy Act*. It will not be disclosed to any persons without the patient's consent. The information you provide will be relevant to and used solely to (a) provide PharmaCare benefits for the medication requested, (b) to implement, monitor and evaluate this and other Ministry programs, and (c) to manage and plan for the health system generally. If you have any questions about the collection or use of this information, call Health Insurance BC from Vancouver at 1-604-683-7151 or from elsewhere in BC toll free at 1-800-663-7100 and ask to consult a pharmacist concerning the Special Authority process.

I have discussed with the patient that the purpose of releasing their information to PharmaCare is to obtain Special Authority for prescription coverage and for the purposes set out here.

Prescriber's Signature (Mandatory)

PharmaCare may request additional documentation to support this Special Authority request.
Actual reimbursement is subject to the rules of a patient's PharmaCare plan, including any annual deductible requirement, and to any other applicable PharmaCare pricing policy.

PHARMACARE USE ONLY

STATUS | EFFECTIVE DATE (YYYY / MM / DD) | DURATION OF APPROVAL

Print | Clear Form

For use in women with postmenopausal osteoporosis or men with osteoporosis with clinical or radiographically documented fracture due to osteoporosis. Form **MUST** indicate that bisphosphonate use is contraindicated due to hypersensitivity or patient has abnormalities of the esophagus.

For primary prevention of osteoporotic fractures in women with breast cancer who are receiving aromatase inhibitor therapy.

Pr prolia® denosumab injection

REVIEWED BY PAAB

Available under the Alberta Health & Wellness Drug Benefit List via Special Authorization[1]

Prolia® (denosumab injection) is indicated:[2]

- for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- as a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- as a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- as a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- as a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- as a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling Amgen at 1-866-502-6436.

CRITERIA:[1]

For the treatment of osteoporosis in patients who have a high 10-year risk (i.e. greater than 20%) of experiencing a major osteoporotic fracture OR a moderate 10-year fracture risk (10-20%) and have experienced a prior fragility fracture.

AND at least one of the following:

1) For whom oral bisphosphonates are contraindicated due to drug-induced hypersensitivity (i.e. immunologically mediated); **OR**
2) For whom oral bisphosphonates are contraindicated due to an abnormality of the esophagus which delays esophageal emptying; **OR**
3) For whom bisphosphonates are contraindicated due to severe renal impairment (i.e. creatinine clearance <35 mL/min); **OR**
4) Who have demonstrated severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate; **OR**
5) Who had an unsatisfactory response (defined as a fragility fracture despite adhering to oral alendronate or risedronate treatment fully for 1 year and evidence of a decline in BMD below pretreatment baseline level).

Note: Fracture risk can be determined by the World Health Organization's Fracture Risk Assessment Tool (FRAX) or the most recent (2010) version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

Special authorization may be granted for 12 months. Patients will be limited to receiving one dose of denosumab per prescription at their pharmacy. Coverage cannot be provided for two or more osteoporosis medications (alendronate, denosumab, raloxifene, risedronate, zoledronic acid) when these medications are intended for use as combination therapy. Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe. Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/mL injection. All requests for denosumab must be completed using the Denosumab/Zoledronic Acid for Osteoporosis Special Authorization Request Form (ABC 60007).

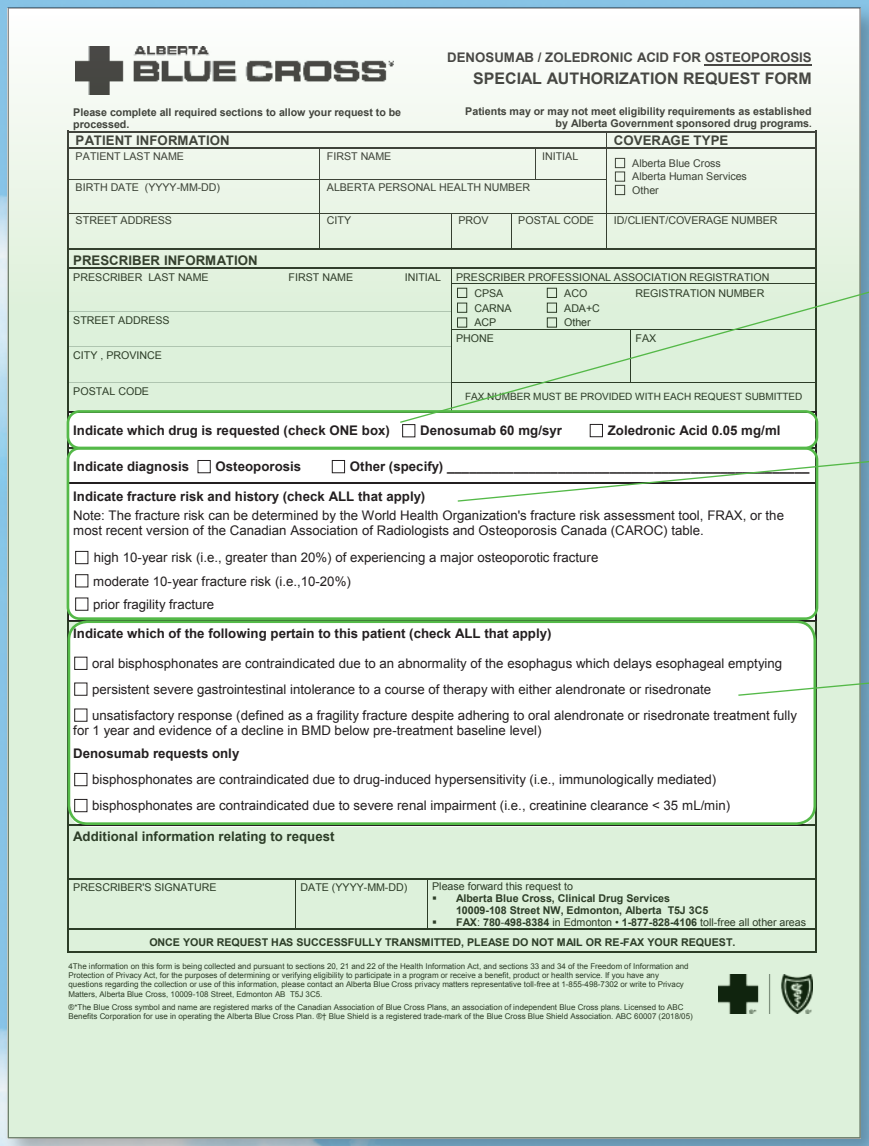
CAN-162-1022-80065-23E

Pr prolia® denosumab injection

REVIEWED BY PAAB

References: 1. Alberta Health – Drug Benefit List. Available at: https://idbl.ab.bluecross.ca/idbl/drugDetails?_cid=1b0efdec-f03a-4807-807c-33a14468bf33&id=0000046113&intchg_grp_nbr=1&detailId=9925236. Accessed October 2, 2023. **2.** Prolia (denosumab injection) Product Monograph. Amgen Canada Inc., December 21, 2022.

Alberta Blue Cross Form – "How To"



ALBERTA BLUE CROSS®

DENOSUMAB / ZOLEDRONIC ACID FOR OSTEOPOROSIS
SPECIAL AUTHORIZATION REQUEST FORM

Please complete all required sections to allow your request to be processed.

Patients may or may not meet eligibility requirements as established by Alberta Government sponsored drug programs.

PATIENT INFORMATION

PATIENT LAST NAME	FIRST NAME	INITIAL	COVERAGE TYPE
BIRTH DATE (YYYY-MM-DD)	ALBERTA PERSONAL HEALTH NUMBER		☐ Alberta Blue Cross ☐ Alberta Human Services ☐ Other
STREET ADDRESS	CITY / PROV / POSTAL CODE		ID/CLIENT/COVERAGE NUMBER

PRESCRIBER INFORMATION

PRESCRIBER LAST NAME / FIRST NAME / INITIAL	PRESCRIBER PROFESSIONAL ASSOCIATION REGISTRATION
STREET ADDRESS	☐ CPSA ☐ ACO ☐ CARNA ☐ ADA+C ☐ ACP ☐ Other — REGISTRATION NUMBER
CITY , PROVINCE	PHONE / FAX
POSTAL CODE	FAX NUMBER MUST BE PROVIDED WITH EACH REQUEST SUBMITTED

Indicate which drug is requested (check ONE box) ☐ **Denosumab 60 mg/syr** ☐ **Zoledronic Acid 0.05 mg/ml**

Indicate diagnosis ☐ **Osteoporosis** ☐ **Other (specify)** _____

Indicate fracture risk and history (check ALL that apply)

Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

☐ high 10-year risk (i.e., greater than 20%) of experiencing a major osteoporotic fracture
☐ moderate 10-year fracture risk (i.e.,10-20%)
☐ prior fragility fracture

Indicate which of the following pertain to this patient (check ALL that apply)

☐ oral bisphosphonates are contraindicated due to an abnormality of the esophagus which delays esophageal emptying
☐ persistent severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate
☐ unsatisfactory response (defined as a fragility fracture despite adhering to oral alendronate or risedronate treatment fully for 1 year and evidence of a decline in BMD below pre-treatment baseline level)

Denosumab requests only

☐ bisphosphonates are contraindicated due to drug-induced hypersensitivity (i.e., immunologically mediated)
☐ bisphosphonates are contraindicated due to severe renal impairment (i.e., creatinine clearance < 35 mL/min)

Additional information relating to request

PRESCRIBER'S SIGNATURE	DATE (YYYY-MM-DD)	Please forward this request to
		• **Alberta Blue Cross, Clinical Drug Services** **10009-108 Street NW, Edmonton, Alberta T5J 3C5** • **FAX**: **780-498-8384** in Edmonton • **1-877-828-4106** toll-free all other areas

ONCE YOUR REQUEST HAS SUCCESSFULLY TRANSMITTED, PLEASE DO NOT MAIL OR RE-FAX YOUR REQUEST.

4The information on this form is being collected and pursuant to sections 20, 21 and 22 of the Health Information Act, and sections 33 and 34 of the Freedom of Information and Protection of Privacy Act, for the purposes of determining or verifying eligibility to participate in a program or receive a benefit, product or health service. If you have any questions regarding the collection or use of this information, please contact an Alberta Blue Cross privacy matters representative toll-free at 1-855-498-7302 or write to Privacy Matters, Alberta Blue Cross, 10009-108 Street, Edmonton AB T5J 3C5.

®†The Blue Cross symbol and name are registered marks of the Canadian Association of Blue Cross Plans, an association of independent Blue Cross plans. Licensed to ABC Benefits Corporation for use in operating the Alberta Blue Cross Plan. ®† Blue Shield is a registered trade-mark of the Blue Cross Blue Shield Association. ABC 60007 (2018/05)

Indicate the requested drug

Form **MUST** indicate diagnosis and fracture risk/history for male and female patients

AND at least **ONE** of the following:

Pr prolia® denosumab injection

REVIEWED BY PAAB

Available for men and postmenopausal women with osteoporosis under the Saskatchewan Drug Plan's Exception Drug Status (EDS) Program[1]

Prolia® (denosumab injection) is indicated:[2]

- for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- as a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- as a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- as a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- as a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- as a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling Amgen at 1-866-502-6436.

CRITERIA:[1]

For men and postmenopausal women with osteoporosis

To increase bone mass in men or postmenopausal women with osteoporosis who are at a high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy, where the following clinical criteria are met:[1]

- High fracture risk*, **AND**
- Contraindication to oral bisphosphonates.†

*High fracture risk is defined as either:
- Moderate 10-year fracture risk (10% to 20%) with a prior fragility fracture;

OR
- High 10-year fracture risk (≥20%).

Fracture risks above as defined by either the CAROC tool or the World Health Organization's FRAX tool.

† Notes:
- Bisphosphonate failure will be defined as a fragility fracture and/or evidence of a decline in bone mineral density below pretreatment baseline levels, despite adherence for one year.
- Contraindication to oral bisphosphonates will be considered. Contraindications include renal impairment, hypersensitivity and abnormalities of the esophagus (e.g. esophageal stricture or achalasia).

For men on ADT for prostate cancer and women on AI for breast cancer

For the treatment of osteoporosis in patients with moderate-high 10-year fracture risk (10% or more) and one of the following:[1]

- Men on androgen deprivation therapy for prostate cancer; **OR**
- Women on aromatase inhibitor therapy for breast cancer.

ADT=androgen deprivation therapy; AI=aromatase inhibitor; CAROC=Canadian Association of Radiologists and Osteoporosis Canada; EDS=exception drug status; FRAX=Fracture Risk Assessment

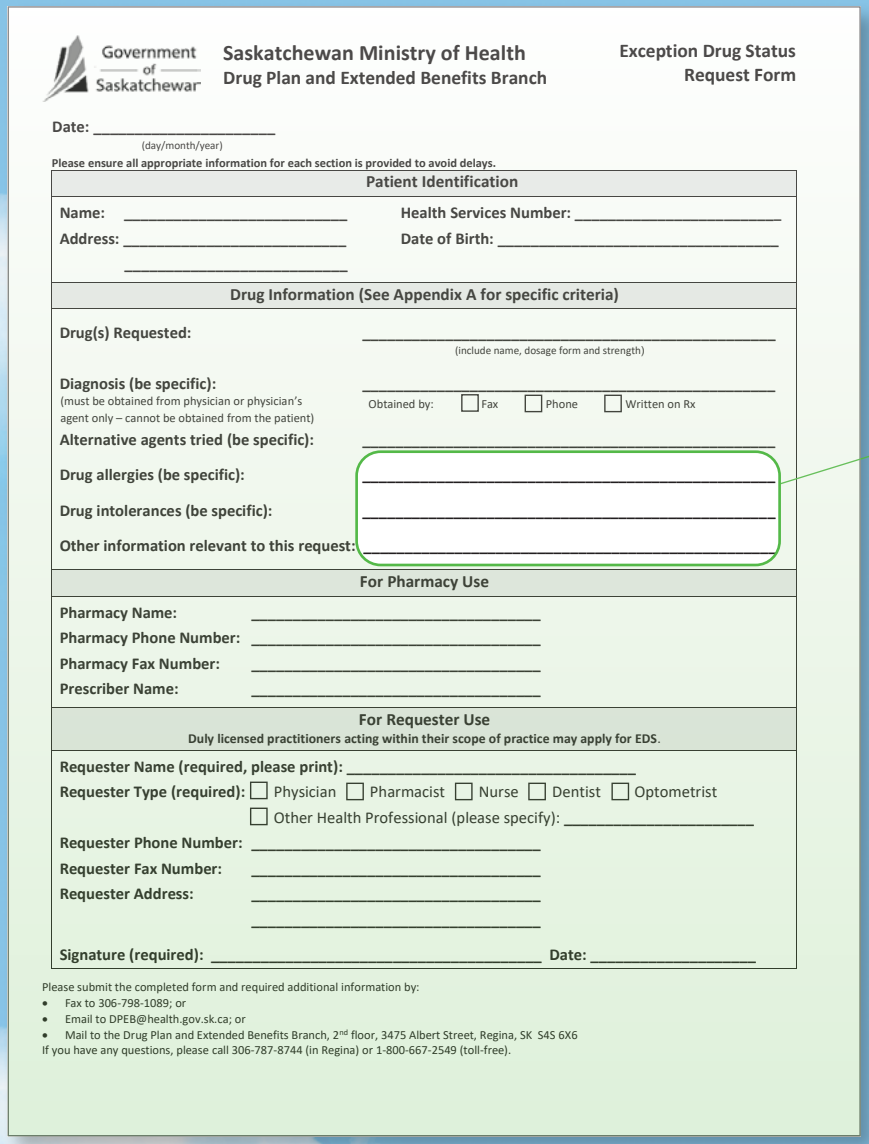
CAN-162-1022-80065-23E

Pr prolia® denosumab injection

REVIEWED BY PAAB

References: 1. Saskatchewan Online Formulary. Available at: https://formulary.drugplan.ehealthsask.ca/SearchFormulary/BG/871368. Accessed October 2, 2023. **2.** Prolia (denosumab injection) Product Monograph. Amgen Canada Inc., December 21, 2022.

Saskatchewan Form – "How To"



Government of Saskatchewan

Saskatchewan Ministry of Health
Drug Plan and Extended Benefits Branch

Exception Drug Status Request Form

Date: _____
(day/month/year)

Please ensure all appropriate information for each section is provided to avoid delays.

Patient Identification

Name: _____ Health Services Number: _____
Address: _____ Date of Birth: _____
_____

Drug Information (See Appendix A for specific criteria)

Drug(s) Requested: _____
(include name, dosage form and strength)

Diagnosis (be specific): _____
(must be obtained from physician or physician's agent only – cannot be obtained from the patient)
Obtained by: ☐ Fax ☐ Phone ☐ Written on Rx

Alternative agents tried (be specific): _____

Drug allergies (be specific): _____

Drug intolerances (be specific): _____

Other information relevant to this request: _____

For Pharmacy Use

Pharmacy Name: _____
Pharmacy Phone Number: _____
Pharmacy Fax Number: _____
Prescriber Name: _____

For Requester Use

Duly licensed practitioners acting within their scope of practice may apply for EDS.

Requester Name (required, please print): _____
Requester Type (required): ☐ Physician ☐ Pharmacist ☐ Nurse ☐ Dentist ☐ Optometrist
☐ Other Health Professional (please specify): _____
Requester Phone Number: _____
Requester Fax Number: _____
Requester Address: _____
_____
Signature (required): _____ Date: _____

Please submit the completed form and required additional information by:
- Fax to 306-798-1089; or
- Email to DPEB@health.gov.sk.ca; or
- Mail to the Drug Plan and Extended Benefits Branch, 2nd floor, 3475 Albert Street, Regina, SK S4S 6X6

If you have any questions, please call 306-787-8744 (in Regina) or 1-800-667-2549 (toll-free).

Form **MUST** indicate that patient with osteoporosis is:

- At high risk of fracture or failed or is intolerant to other available osteoporosis therapies, where the following clinical criteria are met: high risk of fracture, **AND** contraindication to bisphosphonates (including renal impairment, hypersensitivity and abnormalities of the esophagus).
- On ADT for prostate cancer (men) or AI for breast cancer (women) and has moderate-high 10-year fracture risk.

Pr prolia® denosumab injection

REVIEWED BY PAAB

Available under the Manitoba Drug Benefits and Interchangeability Formulary's Exception Drug Status Program[1]

Prolia® (denosumab injection) is indicated:[2]

- for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- as a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- as a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- as a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- as a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- as a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling Amgen at 1-866-502-6436.

CRITERIA:[1]

To increase bone mass in men or postmenopausal women with osteoporosis at a high risk for fracture OR who have failed OR are intolerant to other available osteoporosis therapy, where the following clinical criteria are met:

- High fracture risk defined as either:
  - Moderate 10-year fracture risk (10-20%) as defined by either the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture

OR

  - High 10-year fracture risk (≥20%) as defined by either the CAROC or FRAX tool

AND

- Contraindication to oral bisphosphonates

Notes: Bisphosphonate failure will be defined as a fragility fracture and/or evidence of a decline in bone mineral density below pretreatment baseline levels, despite adherence for one year. Contraindication to oral bisphosphonates will be considered, including: renal impairment, hypersensitivity and abnormalities of the esophagus (e.g. esophageal stricture or achalasia).

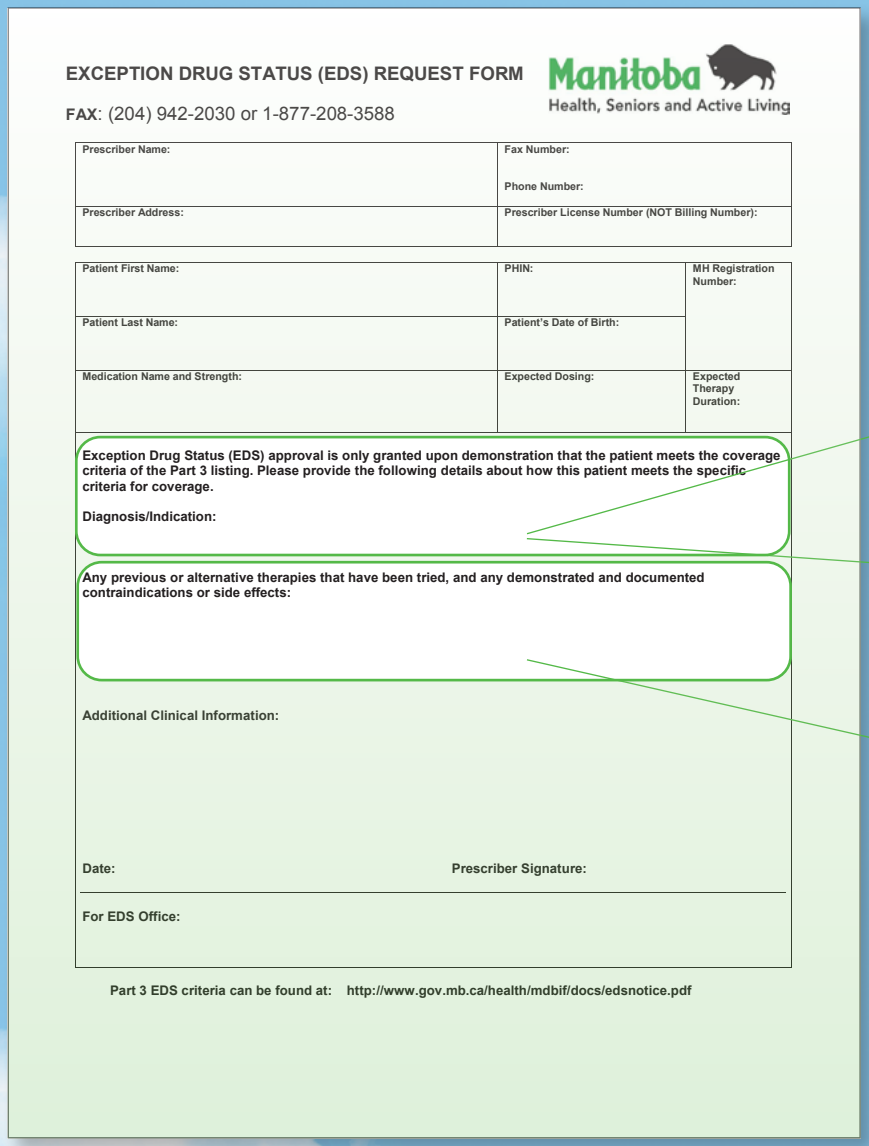
CAN-162-1022-80065-23E

prolia® denosumab injection

REVIEWED BY PAAB

References: 1. Manitoba Formulary. Exception Drug Status (EDS). Available at: https://www.gov.mb.ca/health/mdbif/docs/edsnotice.pdf. Accessed October 2, 2023. **2.** Prolia (denosumab injection) Product Monograph. Amgen Canada Inc., December 21, 2022.

Manitoba Form – "How To"



EXCEPTION DRUG STATUS (EDS) REQUEST FORM

Manitoba
Health, Seniors and Active Living

FAX: (204) 942-2030 or 1-877-208-3588

Prescriber Name:	Fax Number: Phone Number:
Prescriber Address:	Prescriber License Number (NOT Billing Number):

Patient First Name:	PHIN:	MH Registration Number:
Patient Last Name:	Patient's Date of Birth:	
Medication Name and Strength:	Expected Dosing:	Expected Therapy Duration:

Exception Drug Status (EDS) approval is only granted upon demonstration that the patient meets the coverage criteria of the Part 3 listing. Please provide the following details about how this patient meets the specific criteria for coverage.

Diagnosis/Indication:

Any previous or alternative therapies that have been tried, and any demonstrated and documented contraindications or side effects:

Additional Clinical Information:

Date: **Prescriber Signature:**

For EDS Office:

Part 3 EDS criteria can be found at: http://www.gov.mb.ca/health/mdbif/docs/edsnotice.pdf

For use in men or postmenopausal women with osteoporosis at high risk of fracture **OR** who have failed **OR** are intolerant to other available osteoporosis therapy

Form **MUST** include clinical criteria indicating high fracture risk

AND previous therapies tried and any contraindications and/or side effects to bisphosphonates

Requests can be submitted by telephone, mail or fax. A toll-free line with an electronic message system is available exclusively for requests on a 24-hour basis. The telephone number to access this line is (204) 788-6388 or 1-800-557-4303.

Pr prolia® denosumab injection

REVIEWED BY PAAB

Available for both men and postmenopausal women with osteoporosis by the Ontario formulary and most private drug plans[1]

Prolia® (denosumab injection) is indicated:[2]

- for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- as a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- as a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- as a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- as a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- as a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling Amgen at 1-866-502-6436.

CRITERIA:[1]

To increase bone mass in males and postmenopausal females with osteoporosis who meet the following criteria:[1]

High risk for fracture*; and

Failed other available osteoporosis therapy (i.e., fragility fracture **OR** evidence of a decline in bone mineral density below pretreatment baseline levels) despite adherence for one year.	For whom oral bisphosphonates are contraindicated due to hypersensitivity **OR** abnormalities of the esophagus (e.g., esophageal stricture or achalasia) **OR** inability to stand or sit upright for at least 30 minutes.
♀ LU Code 428 ♂ LU Code 515	♀ LU Code 429 ♂ LU Code 516

* High fracture risk is defined as:[1]
- A prior fragility fracture AND a moderate 10-year fracture risk (10% to 20%); OR
- A high 10-year fracture risk (≥20%); OR
- Where a patient's 10-year fracture risk is less than the thresholds defined above, a high fracture risk based on evaluation of clinical risk factors for fracture.

All above definitions are based on the CAROC or FRAX tool.

Notes:
- Use of the CAROC or FRAX tool may underestimate fracture risk in certain circumstances and may not include all risk factors.
- In all cases, patients on Prolia must not be receiving concomitant bisphosphonate therapy. Recommended dose of Prolia is a single SC injection of 60 mg, once every 6 months.

LU Authorization Period: Indefinite.

CAROC=Canadian Association of Radiologists and Osteoporosis Canada; FRAX=Fracture Risk Assessment

CAN-162-1022-80065-23E

Pr prolia® denosumab injection

REVIEWED BY PAAB

References: 1. Ontario Drug Benefit Formulary. Limited Use. https://www.formulary.health.gov.on.ca/formulary/. Accessed October 4, 2023.
2. Prolia (denosumab injection) Product Monograph. Amgen Canada Inc., December 21, 2022.

Available for both postmenopausal women (code MS153) and men with osteoporosis under *Régie de l'assurance maladie du Québec* (RAMQ) via Special Authorization[1]

Prolia® is (denosumab injection) indicated:[2]

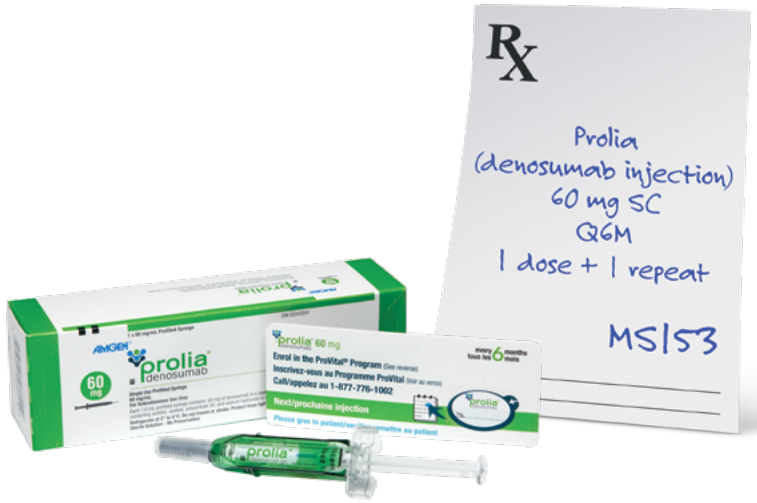
- for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- as a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- as a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- as a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- as a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- as a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling Amgen at 1-866-502-6436.

CRITERIA:[1]

- **For the treatment of postmenopausal osteoporosis (PMO) in women who cannot take an oral bisphosphonate due to serious intolerance or contraindication.**
- **For the treatment of osteoporosis in men at high risk of fracture who cannot take an oral bisphosphonate due to serious intolerance or contraindication.**

"RAMQ" is the official mark of the *Régie de l'assurance maladie du Québec*.



Prolia is also covered by all private drug plans in Quebec.

CAN-162-1022-80065-23E

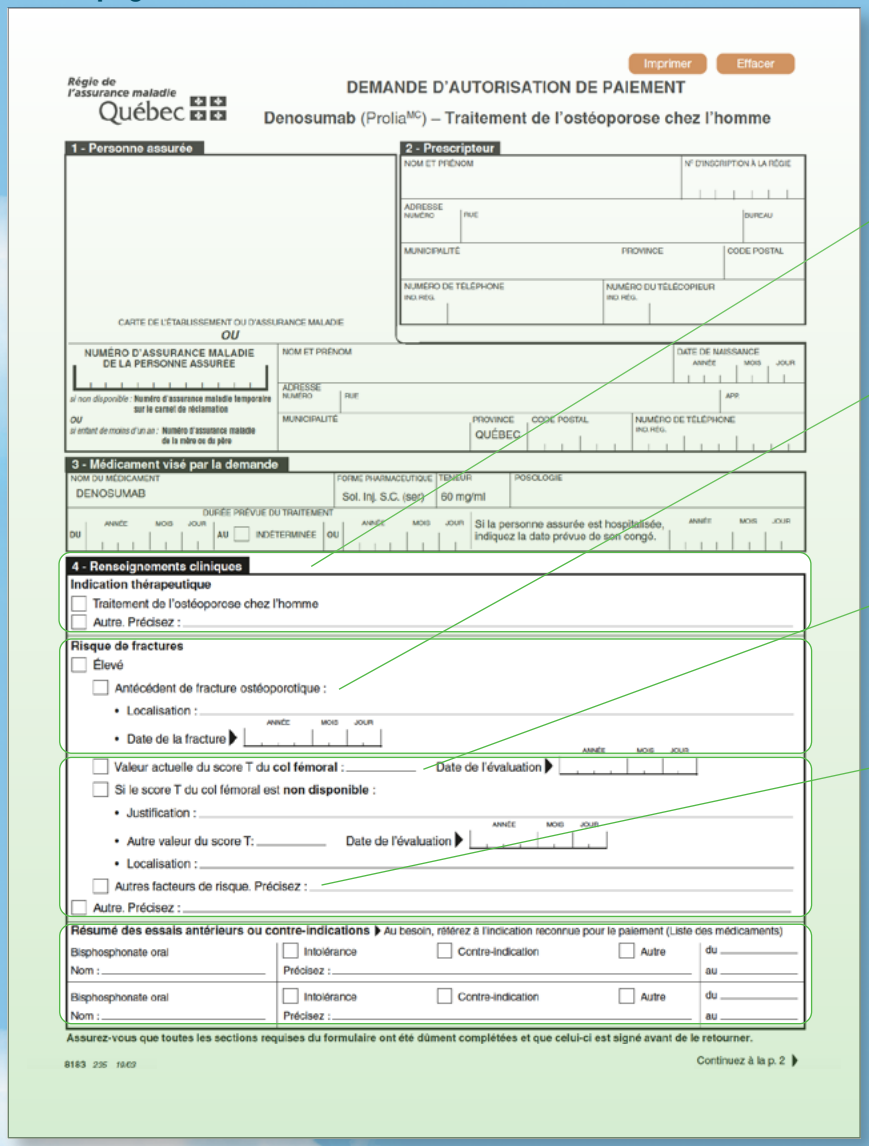
prolia® denosumab injection

REVIEWED BY PAAB

References: 1. RAMQ List of medications. September 27, 2023. Available at: https://www.ramq.gouv.qc.ca/sites/default/files/documents/non_indexes/liste-med-2023-09-27-en.pdf. Accessed October 2, 2023. **2.** Prolia (denosumab injection) Product Monograph. Amgen Canada Inc., December 21, 2022.

RAMQ Form – "How To"

Front (page 1/2)



Imprimer Effacer

Régie de l'assurance maladie Québec

DEMANDE D'AUTORISATION DE PAIEMENT

Denosumab (Prolia[MC]) – Traitement de l'ostéoporose chez l'homme

1 - Personne assurée

CARTE DE L'ÉTABLISSEMENT OU D'ASSURANCE MALADIE

OU

NUMÉRO D'ASSURANCE MALADIE DE LA PERSONNE ASSURÉE

si non disponible : Numéro d'assurance maladie temporaire sur le carnet de réclamation

OU

si enfant de moins d'un an : Numéro d'assurance maladie de la mère ou du père

NOM ET PRÉNOM

DATE DE NAISSANCE ANNÉE MOIS JOUR

ADRESSE NUMÉRO RUE APP

MUNICIPALITÉ PROVINCE QUÉBEC CODE POSTAL NUMÉRO DE TÉLÉPHONE IND. RÉG.

2 - Prescripteur

NOM ET PRÉNOM N° D'INSCRIPTION À LA RÉGIE

ADRESSE NUMÉRO RUE BUREAU

MUNICIPALITÉ PROVINCE CODE POSTAL

NUMÉRO DE TÉLÉPHONE IND. RÉG. NUMÉRO DU TÉLÉCOPIEUR IND. RÉG.

3 - Médicament visé par la demande

NOM DU MÉDICAMENT: DENOSUMAB

FORME PHARMACEUTIQUE: Sol. Inj. S.C. (ser)

TENEUR: 60 mg/ml

POSOLOGIE

DURÉE PRÉVUE DU TRAITEMENT

DU ANNÉE MOIS JOUR AU ☐ INDÉTERMINÉE OU ANNÉE MOIS JOUR

Si la personne assurée est hospitalisée, indiquez la date prévue de son congé. ANNÉE MOIS JOUR

4 - Renseignements cliniques

Indication thérapeutique

☐ Traitement de l'ostéoporose chez l'homme

☐ Autre. Précisez :

Risque de fractures

☐ Élevé

☐ Antécédent de fracture ostéoporotique :

- Localisation :
- Date de la fracture ▶ ANNÉE MOIS JOUR

☐ Valeur actuelle du score T du **col fémoral** : Date de l'évaluation ▶ ANNÉE MOIS JOUR

☐ Si le score T du col fémoral est **non disponible** :

- Justification :
- Autre valeur du score T: Date de l'évaluation ▶ ANNÉE MOIS JOUR
- Localisation :

☐ Autres facteurs de risque. Précisez :

☐ Autre. Précisez :

Résumé des essais antérieurs ou contre-indications ▶ Au besoin, référez à l'indication reconnue pour le paiement (Liste des médicaments)

Bisphosphonate oral Nom :	☐ Intolérance Précisez :	☐ Contre-indication	☐ Autre	du au
Bisphosphonate oral Nom :	☐ Intolérance Précisez :	☐ Contre-indication	☐ Autre	du au

Assurez-vous que toutes les sections requises du formulaire ont été dûment complétées et que celui-ci est signé avant de le retourner.

8183 235 19-03

Continuez à la p. 2 ▶

MALE OSTEOPOROSIS

Specify the indication for use.

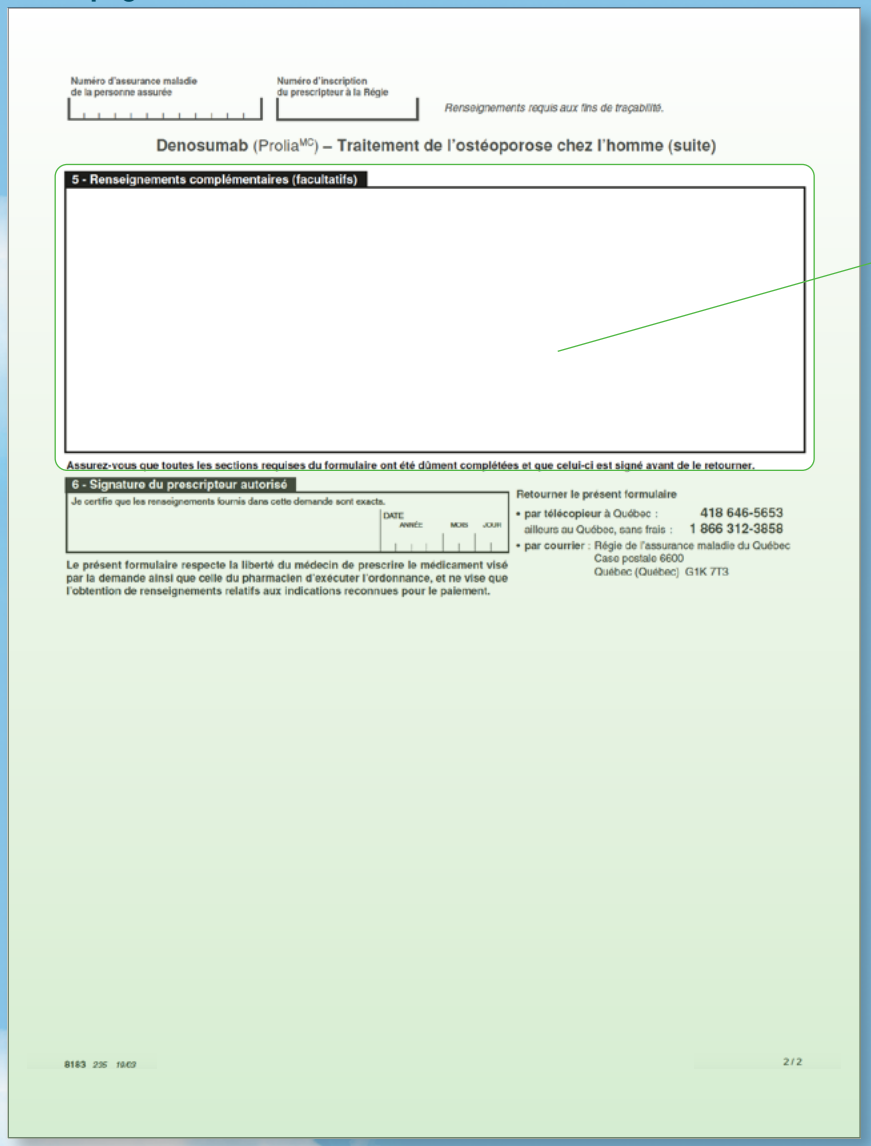
Form **MUST** indicate that the patient is at a high risk of fracture. Indicate where and when the prior fracture(s) occurred, the T-score with date and any additional risk factors.

If applicable, include specific fracture date. Femoral T score is preferred. Include as many details as possible (e.g., bisphosphonate taken and for how long, reason why patient was discontinued and other risk factors).

Form **MUST** indicate that bisphosphonates cannot be used due to serious intolerance or contraindication.

RAMQ Form – "How To"

Back (page 2/2)



Numéro d'assurance maladie de la personne assurée

Numéro d'inscription du prescripteur à la Régie

Renseignements requis aux fins de traçabilité.

Denosumab (Prolia[MC]) – Traitement de l'ostéoporose chez l'homme (suite)

5 - Renseignements complémentaires (facultatifs)

Assurez-vous que toutes les sections requises du formulaire ont été dûment complétées et que celui-ci est signé avant de le retourner.

6 - Signature du prescripteur autorisé

Je certifie que les renseignements fournis dans cette demande sont exacts.

DATE ANNÉE MOIS JOUR

Le présent formulaire respecte la liberté du médecin de prescrire le médicament visé par la demande ainsi que celle du pharmacien d'exécuter l'ordonnance, et ne vise que l'obtention de renseignements relatifs aux indications reconnues pour le paiement.

Retourner le présent formulaire

- par télécopieur à Québec : 418 646-5653
  ailleurs au Québec, sans frais : 1 866 312-3858
- par courrier : Régie de l'assurance maladie du Québec
  Case postale 6600
  Québec (Québec) G1K 7T3

8183 235 19-03

2 / 2

MALE OSTEOPOROSIS

Optional space to add additional details, if applicable (e.g., indicate if the patient has severe osteoporosis).

Pr prolia® denosumab injection

REVIEWED BY PAAB

Available under the Nova Scotia Health & Wellness Public Drug Plan – Exception Status Benefit[1]

Prolia® (denosumab injection) is indicated:[2]

- for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- as a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- as a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- as a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- as a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- as a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling Amgen at 1-866-502-6436.

CRITERIA:[1]

For the treatment of osteoporosis in postmenopausal women and male patients who meet the following criteria:

- Have a contraindication to oral bisphosphonates; and
- High risk for fracture, or refractory or intolerant to other available osteoporosis therapies.

CLINICAL NOTES:

- Refractory is defined as a fragility fracture or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year to other available osteoporosis therapies.
- High fracture risk defined as:
  - Moderate 10-year fracture risk (10% to 20%) as defined by the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture; or
  - High 10-year fracture risk (≥20%) as defined by CAROC or FRAX tool.

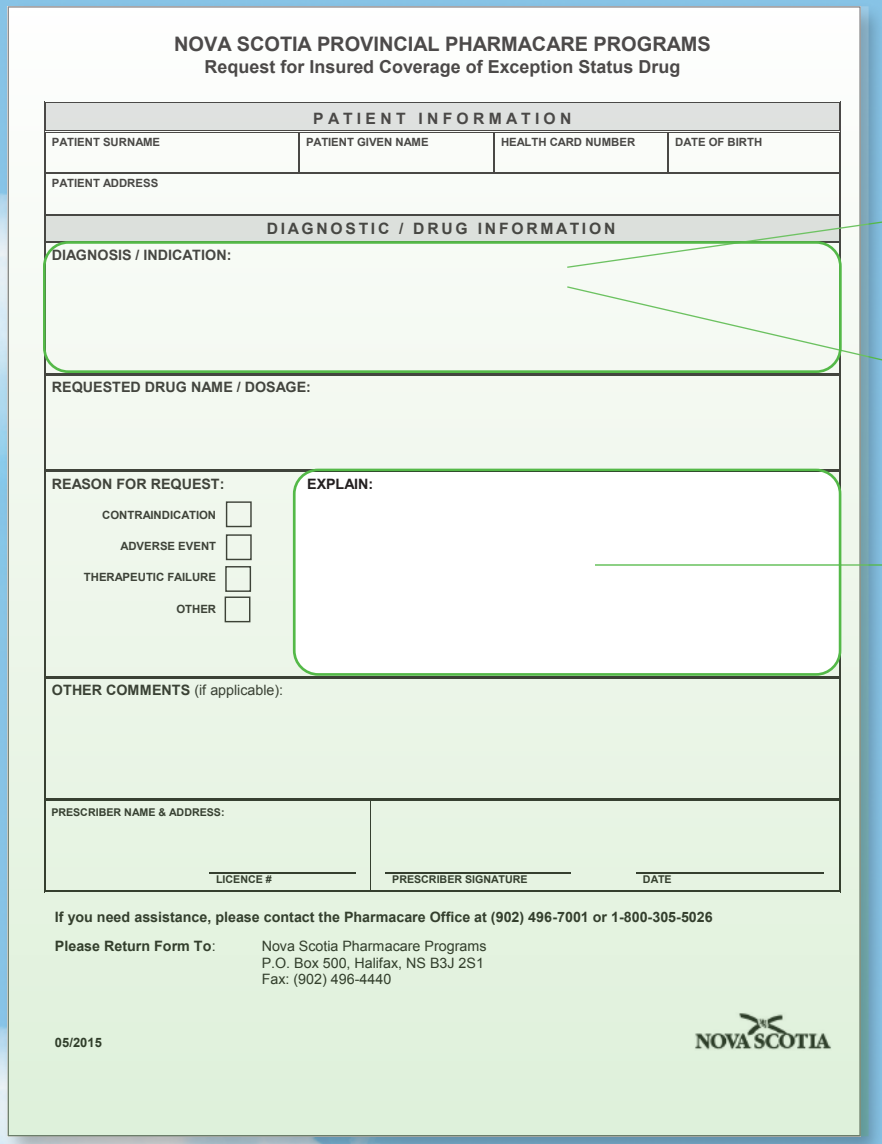
CAN-162-1022-80065-23E

Pr prolia® denosumab injection

REVIEWED BY PAAB

References: 1. Nova Scotia Formulary. Available at: https://novascotia.ca/dhw/pharmacare/documents/formulary.pdf. Accessed October 2, 2023.
2. Prolia (denosumab injection) Product Monograph. Amgen Canada Inc., December 21, 2022.

Nova Scotia Form – "How To"



NOVA SCOTIA PROVINCIAL PHARMACARE PROGRAMS
Request for Insured Coverage of Exception Status Drug

PATIENT INFORMATION

PATIENT SURNAME	PATIENT GIVEN NAME	HEALTH CARD NUMBER	DATE OF BIRTH

PATIENT ADDRESS

DIAGNOSTIC / DRUG INFORMATION

DIAGNOSIS / INDICATION:

REQUESTED DRUG NAME / DOSAGE:

REASON FOR REQUEST:
- CONTRAINDICATION ☐
- ADVERSE EVENT ☐
- THERAPEUTIC FAILURE ☐
- OTHER ☐

EXPLAIN:

OTHER COMMENTS (if applicable):

PRESCRIBER NAME & ADDRESS:

LICENCE # | PRESCRIBER SIGNATURE | DATE

If you need assistance, please contact the Pharmacare Office at (902) 496-7001 or 1-800-305-5026

Please Return Form To: Nova Scotia Pharmacare Programs
P.O. Box 500, Halifax, NS B3J 2S1
Fax: (902) 496-4440

05/2015

NOVA SCOTIA

For use in men or postmenopausal women with osteoporosis at high risk of fracture **OR** who have failed **OR** are intolerant to other available osteoporosis therapy

Form **MUST** include clinical criteria indicating high fracture risk

AND previous therapies tried and any contraindications and/or side effects to bisphosphonates

Pr prolia® denosumab injection

REVIEWED BY PAAB

Available under the Newfoundland and Labrador Public Drug Program via Special Authorization[1]

Prolia® (denosumab injection) is indicated:[2]

- for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- as a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- as a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- as a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- as a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- as a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling Amgen at 1-866-502-6436.

CRITERIA:[1]

For the treatment of osteoporosis in patients who have:

- A high fracture risk

AND

- A contraindication, severe gastrointestinal intolerance, or are refractory to bisphosphonates.

CLINICAL NOTES:

1. Refractory is defined as a fragility fracture or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year to osteoporosis therapy.
2. High fracture risk is defined as:
   - Moderate 10-year fracture risk (10% to 20%) as defined by the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture; or
   - High 10-year fracture risk (≥20%) as defined by the CAROC or FRAX tool.

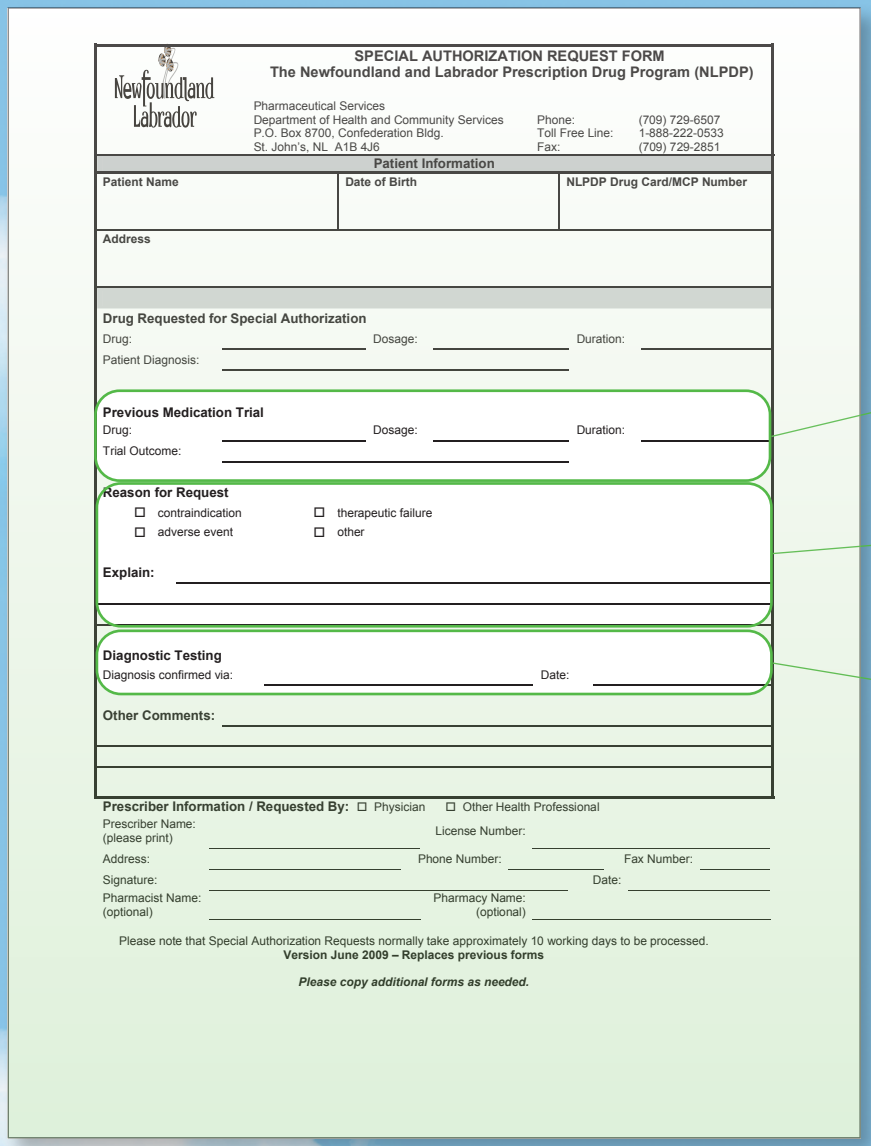
CAN-162-1022-80065-23E

Pr prolia® denosumab injection

REVIEWED BY PAAB

References: 1. Newfoundland and Labrador. Health and Community Services. Special Authorization Drug Products. Available at: https://www.gov.nl.ca/hcs/files/Criteria-Sept-2023.pdf. Accessed October 2, 2023. **2.** Prolia (denosumab injection) Product Monograph. Amgen Canada Inc., December 21, 2022.

Newfoundland and Labrador Form – "How To"



Newfoundland Labrador

SPECIAL AUTHORIZATION REQUEST FORM
The Newfoundland and Labrador Prescription Drug Program (NLPDP)

Pharmaceutical Services
Department of Health and Community Services
P.O. Box 8700, Confederation Bldg.
St. John's, NL A1B 4J6

Phone: (709) 729-6507
Toll Free Line: 1-888-222-0533
Fax: (709) 729-2851

Patient Information

Patient Name	Date of Birth	NLPDP Drug Card/MCP Number

Address

Drug Requested for Special Authorization

Drug: _____ Dosage: _____ Duration: _____
Patient Diagnosis: _____

Previous Medication Trial

Drug: _____ Dosage: _____ Duration: _____
Trial Outcome: _____

Reason for Request

☐ contraindication ☐ therapeutic failure
☐ adverse event ☐ other

Explain: _____

Diagnostic Testing

Diagnosis confirmed via: _____ Date: _____

Other Comments: _____

Prescriber Information / Requested By: ☐ Physician ☐ Other Health Professional

Prescriber Name: (please print) _____ License Number: _____
Address: _____ Phone Number: _____ Fax Number: _____
Signature: _____ Date: _____
Pharmacist Name: (optional) _____ Pharmacy Name: (optional) _____

Please note that Special Authorization Requests normally take approximately 10 working days to be processed.
Version June 2009 – Replaces previous forms

Please copy additional forms as needed.

Indicate previous treatment(s) and outcome

Form **MUST** indicate contraindication to bisphosphonate use **AND** high fracture risk OR patient is intolerant OR refractory to available therapies

Form **MUST** indicate the clinical criteria indicating high fracture risk

Pr prolia® denosumab injection

REVIEWED BY PAAB

Available for both men and postmenopausal women with osteoporosis under the New Brunswick Prescription Drug Program via Special Authorization[1]

Prolia® (denosumab injection) is indicated:[2]

- for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- as a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- as a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- as a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- as a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- as a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling Amgen at 1-866-502-6436.

CRITERIA:[1]

For the treatment of osteoporosis in patients who have:[1]

- A high fracture risk, and
- A contraindication, severe gastrointestinal intolerance, or are refractory to bisphosphonates.

CLINICAL NOTES:

1. Refractory is defined as a fragility fracture or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year to osteoporosis therapy.
2. High fracture risk defined as:
   - Moderate 10-year fracture risk (10% to 20%) as defined by the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture; or
   - High 10-year fracture risk (≥20%) as defined by either the CAROC or FRAX tool.

CLAIM NOTES:

Initial approval period: 1 year.
Renewal approval period: Long term.

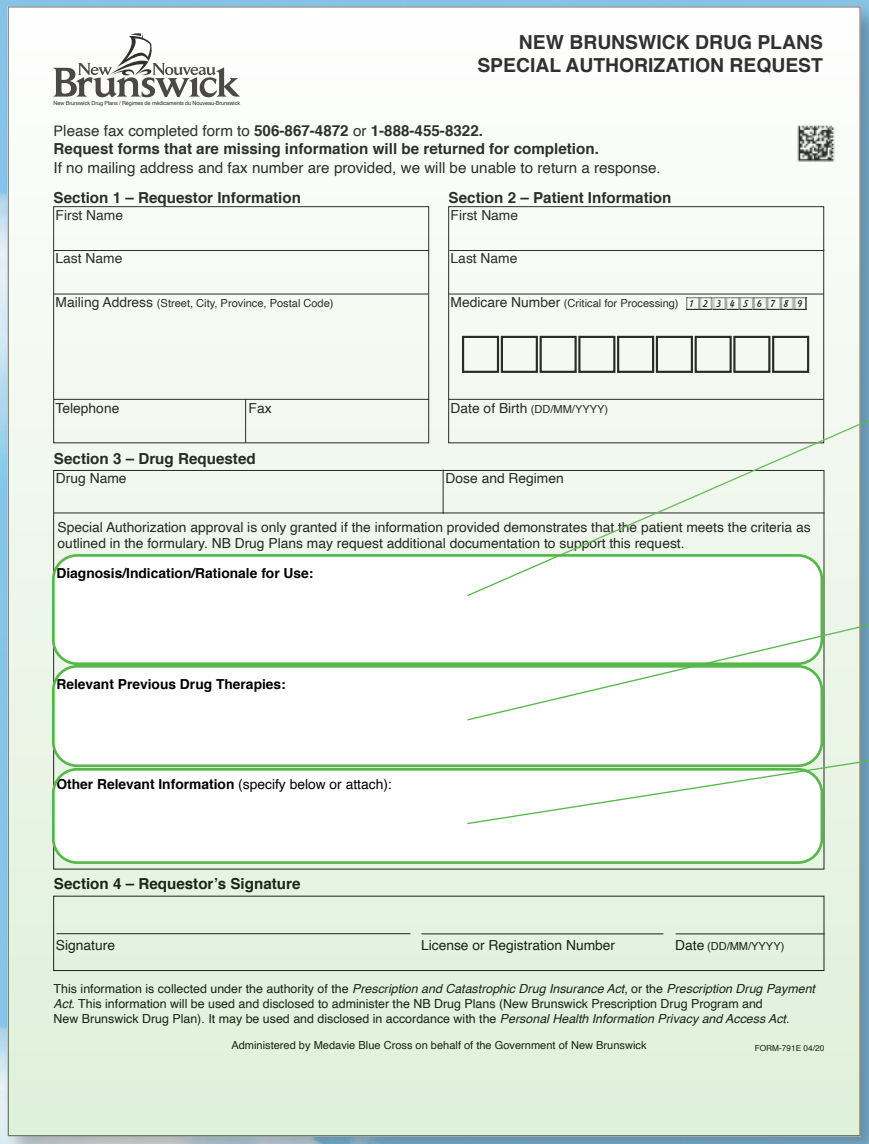
CAN-162-1022-80065-23E

Pr prolia® denosumab injection

REVIEWED BY PAAB

References: 1. New Brunswick Drug Plans Formulary. Available at: https://www2.gnb.ca/content/dam/gnb/Departments/h-s/pdf/en/NBDrugPlan/NewBrunswickDrugPlansFormulary.pdf. Accessed October 2, 2023. **2.** Prolia (denosumab injection) Product Monograph. Amgen Canada Inc., December 21, 2022.

New Brunswick Form – "How To"



New Brunswick / Nouveau-Brunswick

NEW BRUNSWICK DRUG PLANS
SPECIAL AUTHORIZATION REQUEST

Please fax completed form to **506-867-4872** or **1-888-455-8322.**
Request forms that are missing information will be returned for completion.
If no mailing address and fax number are provided, we will be unable to return a response.

Section 1 – Requestor Information

First Name
Last Name
Mailing Address (Street, City, Province, Postal Code)
Telephone | Fax

Section 2 – Patient Information

First Name
Last Name
Medicare Number (Critical for Processing) 1 2 3 4 5 6 7 8 9
Date of Birth (DD/MM/YYYY)

Section 3 – Drug Requested

Drug Name | Dose and Regimen

Special Authorization approval is only granted if the information provided demonstrates that the patient meets the criteria as outlined in the formulary. NB Drug Plans may request additional documentation to support this request.

Diagnosis/Indication/Rationale for Use:

Relevant Previous Drug Therapies:

Other Relevant Information (specify below or attach):

Section 4 – Requestor's Signature

Signature | License or Registration Number | Date (DD/MM/YYYY)

This information is collected under the authority of the *Prescription and Catastrophic Drug Insurance Act*, or the *Prescription Drug Payment Act*. This information will be used and disclosed to administer the NB Drug Plans (New Brunswick Prescription Drug Program and New Brunswick Drug Plan). It may be used and disclosed in accordance with the *Personal Health Information Privacy and Access Act*.

Administered by Medavie Blue Cross on behalf of the Government of New Brunswick

FORM-791E 04/20

For use in patients with osteoporosis in whom bisphosphonate use is contraindicated and where the patient is at high risk of fracture, or refractory or intolerant to other available osteoporosis therapies.

Form **MUST** indicate previous therapies that the patient was refractory to or could not tolerate.

Form **MUST** indicate that bisphosphonate use is contraindicated.

Pr prolia® denosumab injection

REVIEWED BY PAAB

Available under PEI Pharmacare when patients meet Special Authority criteria[1]

Prolia® (denosumab injection) is indicated:[2]

- for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- as a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- as a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- as a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- as a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- as a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

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CRITERIA:[1]

For the treatment of osteoporosis in patients who have:

- A high fracture risk, and
- A contraindication, severe gastrointestinal intolerance, or are refractory to bisphosphonates.

CLINICAL NOTES:

- Refractory is defined as a fragility fracture or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year to other available osteoporosis therapies.
- High fracture risk defined as:
  - Moderate 10-year fracture risk (10% to 20%) as defined by the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture; or
  - High 10-year fracture risk (≥20%) as defined by the CAROC or FRAX tool.

For full details regarding coverage, visit www.healthpei.ca/formulary.

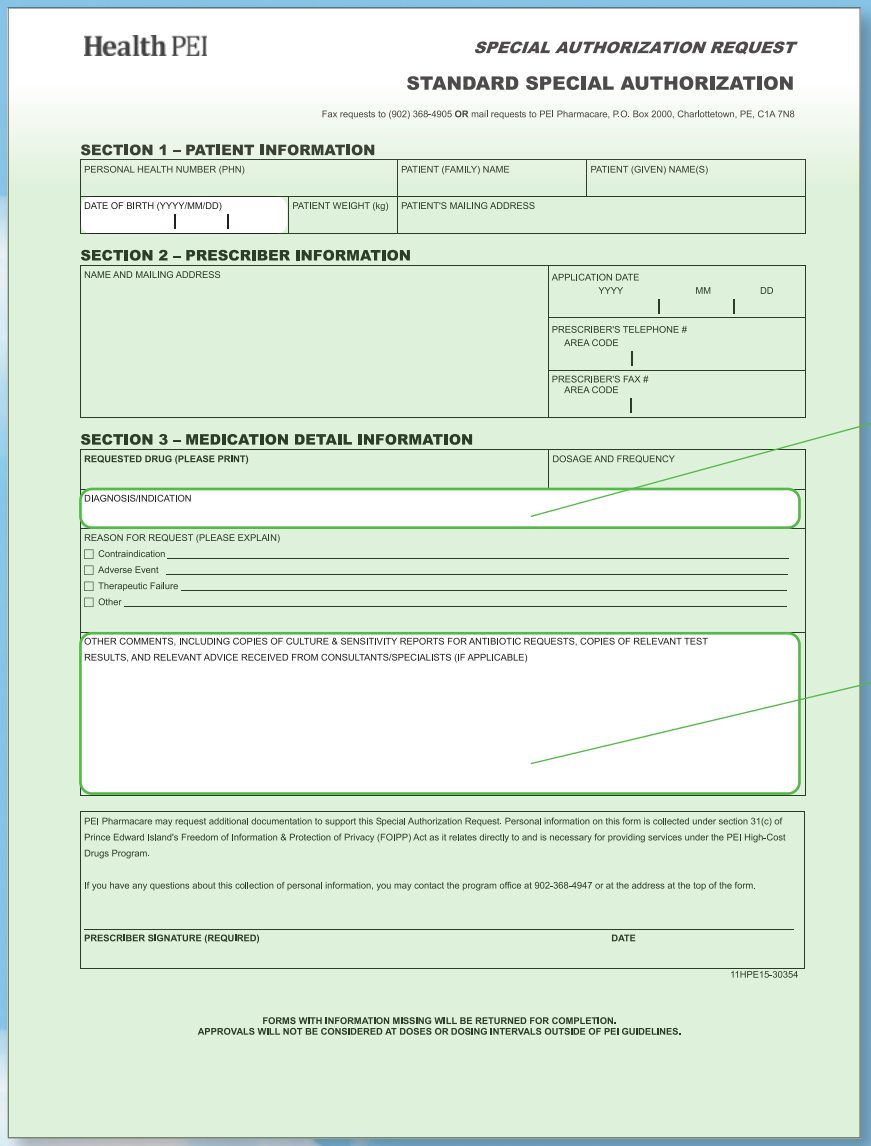
CAN-162-1022-80065-23E

Pr prolia® denosumab injection

REVIEWED BY PAAB

References: 1. Health PEI. P.E.I. Pharmacare Formulary. Available at: https://www.princeedwardisland.ca/sites/default/files/publications/pei_pharmacare_formulary.pdf. Accessed October 2, 2023. **2.** Prolia (denosumab injection) Product Monograph. Amgen Canada Inc., December 21, 2022.

PEI Form – "How To"



Health PEI

SPECIAL AUTHORIZATION REQUEST

STANDARD SPECIAL AUTHORIZATION

Fax requests to (902) 368-4905 **OR** mail requests to PEI Pharmacare, P.O. Box 2000, Charlottetown, PE, C1A 7N8

SECTION 1 – PATIENT INFORMATION

PERSONAL HEALTH NUMBER (PHN)	PATIENT (FAMILY) NAME	PATIENT (GIVEN) NAME(S)
DATE OF BIRTH (YYYY/MM/DD)	PATIENT WEIGHT (kg)	PATIENT'S MAILING ADDRESS

SECTION 2 – PRESCRIBER INFORMATION

NAME AND MAILING ADDRESS	APPLICATION DATE YYYY MM DD
	PRESCRIBER'S TELEPHONE # AREA CODE
	PRESCRIBER'S FAX # AREA CODE

SECTION 3 – MEDICATION DETAIL INFORMATION

REQUESTED DRUG (PLEASE PRINT)	DOSAGE AND FREQUENCY

DIAGNOSIS/INDICATION

REASON FOR REQUEST (PLEASE EXPLAIN)

- ☐ Contraindication
- ☐ Adverse Event
- ☐ Therapeutic Failure
- ☐ Other

OTHER COMMENTS, INCLUDING COPIES OF CULTURE & SENSITIVITY REPORTS FOR ANTIBIOTIC REQUESTS, COPIES OF RELEVANT TEST RESULTS, AND RELEVANT ADVICE RECEIVED FROM CONSULTANTS/SPECIALISTS (IF APPLICABLE)

PEI Pharmacare may request additional documentation to support this Special Authorization Request. Personal information on this form is collected under section 31(c) of Prince Edward Island's Freedom of Information & Protection of Privacy (FOIPP) Act as it relates directly to and is necessary for providing services under the PEI High-Cost Drugs Program.

If you have any questions about this collection of personal information, you may contact the program office at 902-368-4947 or at the address at the top of the form.

PRESCRIBER SIGNATURE (REQUIRED) **DATE**

11HPE15-30354

FORMS WITH INFORMATION MISSING WILL BE RETURNED FOR COMPLETION.
APPROVALS WILL NOT BE CONSIDERED AT DOSES OR DOSING INTERVALS OUTSIDE OF PEI GUIDELINES.

For use in female patients with postmenopausal osteoporosis or male patients with osteoporosis in whom bisphosphonate use is contraindicated and where the patient is at high risk of fracture, or refractory or intolerant to other available osteoporosis therapies.

Form **MUST** indicate that bisphosphonate use is contraindicated, and patient is at high risk for fracture or was refractory to or could not tolerate previous therapies.

Pr prolia® denosumab injection

REVIEWED BY PAAB

Electronic Certificate

Version: 4 . 0

Document Number: CAN-162-1022-80065

Document Name: Prolia IVA Formulary Coverage Slide Deck

Country: Canada

Product: Prolia

Branding: Branded

Type: GRP Material

Sub Type: iDetail Aid

Classification:

Material Intent: Promotional

Expiration Date: 30 Nov 2024

Certification Statement
We certify that the final electronic form of this material is in accordance with the regulations set forth by the health authority (where applicable) for the country of this document, and is a fair and truthful presentation of the facts about the product.

Role	Signature
Savannah Fernandes - Commercial Approval (sferna04@amgen.com)	Meaning: As the Commercial, I approve this document for use. Date: 15-Jan-2024 14:58:37 GMT+0000